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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/775,398	01/31/2001	Christoph Plass	22727/04075	7997

7590

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Pamela A. Docherty  
CALFEE, HALTER & GRISWOLD, LLP  
1400 McDonald Investment Center  
800 Superior Avenue  
Cleveland, OH 44114

EXAMINER

MYERS, CARLA J

ART UNIT

PAPER NUMBER

1634

DATE MAILED: 01/16/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

Application No.

09/775,398

Applicant(s)

PLASS, CHRISTOPH

Examiner

Carla Myers

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1634

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 22 October 2002.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1-39 is/are pending in the application.
- 4a) Of the above claim(s) 4-39 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-3 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

### Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

### Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 6, 7.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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1. Applicant's election of group I, claims 1-3 in Paper No. 11 is acknowledged. Because applicant did not distinctly and specifically point out the supposed errors in the restriction requirement, the election has been treated as an election without traverse (MPEP § 818.03(a)).

***Claim Rejections - 35 USC § 102***

2. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Plass (Oncogene May 20, 1999) 18: 3159-3165).

Plass teaches a method for identifying CpG islands which are preferentially methylated in acute myeloid leukemia, which is a malignant cancer. The reference teaches that RLGS profiling allows for the comparison of methylation patterns in normal versus tumor tissue (page 3159) and states that aberrant methylation in the regulatory regions of expressed genes may play a role in hematologic cancers. To determine whether DNAs are preferentially methylated in acute myeloid leukemia cells, Plass uses the method of RLGS. In particular, Plass teaches a method in which (i) a genomic DNA sample from malignant cells and a genomic DNA sample from non-malignant control cells are separately digested with a infrequently cutting, methylation-sensitive restriction enzyme (Not I); (ii) the digested samples are end labeled; (iii) the labeled samples are cut with a second restriction enzyme, EcoRV; (iv) the labeled restriction fragments of step (iii) are separated by gel electrophoresis in 2 separate gels; (v) the restriction fragments are digested

with a third restriction enzyme, Hinf I, in the gel; (vi) the fragments are subjected to electrophoresis in a direction perpendicular to the first separation; and (vii) the pattern of restriction fragments from the malignant cells is compared to the pattern of restriction fragments from the non-malignant control cells in order to identify CpG islands that are preferentially methylated in malignant acute myeloid leukemia cells (see, for example, page 3164). Plass also teaches cloning the DNA from normal cells which corresponds to the DNA that is preferentially methylated in acute myeloid leukemia cells and teaches determining the sequence of at least a portion of this DNA.

3. Claims 1-3 are rejected under 35 U.S.C. 102(b) as being anticipated by Costello (Nature (2000) 25: 132-138; reference "AJ").

Costello teaches a method for identifying CpG islands which are preferentially methylated in cancer, particularly in the malignant cancer acute myeloid leukemia (page 135 and 137). Costello teaches that the method of RLGS can be used to identify DNAs that are preferentially methylated in acute myeloid leukemia cells. In particular, Costello teaches a method in which (i) a genomic DNA sample from malignant cells and a genomic DNA sample from non-malignant control cells are separately digested with a infrequently cutting, methylation-sensitive restriction enzyme, Not I (see pages 135 and 137); (ii) the digested samples are end labeled; (iii) the labeled samples are cut with a second restriction enzyme, EcoRV; (iv) the labeled restriction fragments of step (iii) are separated by gel electrophoresis in 2 separate gels; (v) the restriction fragments are digested with a third restriction enzyme, Hinf I, in the gel; (vi) the fragments are subjected to electrophoresis in a direction perpendicular to the first separation; and (vii) the pattern of restriction fragments from the malignant cells is

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compared to the pattern of restriction fragments from the non-malignant control cells in order to identify CpG islands that are preferentially methylated in malignant acute myeloid leukemia cells (see, for example, page 137). Costello also teaches cloning the DNA from normal cells which corresponds to the DNA that is preferentially methylated in acute myeloid leukemia cells and other cancer cells and teaches determining the sequence of at least a portion of this DNA (see page 137).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carla Myers whose telephone number is (703) 308-2199. The examiner can normally be reached on Monday-Thursday from 6:30 AM-5:00 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones, can be reached on (703)-308-1152. Papers related to this application may be faxed to Group 1634 via the PTO Fax Center using the fax number (703)-872-9306 or (703)-872-9307 (after final).

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

Carla Myers

January 6, 2003

  
CARLA J. MYERS  
PRIMARY EXAMINER